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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
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18M2/0829
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RAILEY, J. EXAMINER	
ART UNIT	PAPER NUMBER
1804	12
DATE MAILED: 08/29/94	

Below is a communication from the EXAMINER in charge of this application

COMMISSIONER OF PATENTS AND TRADEMARKS

ADVISORY ACTION

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☒ THE PERIOD FOR RESPONSE:

- a) ☒ is extended to run _____ or continues to run 3 MONTHS from the date of the final rejection
- b) ☐ expires three months from the date of the final rejection or as of the mailing date of this Advisory Action, whichever is later. In no event however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

☐ Appellant's Brief is due in accordance with 37 CFR 1.192(a).

☒ Applicant's response to the final rejection, filed 16 AUG 1994 has been considered with the following effect, but it is not deemed to place the application in condition for allowance:

1. ☐ The proposed amendments to the claim and/or specification will not be entered and the final rejection stands because:
- a. ☐ There is no convincing showing under 37 CFR 1.116(b) why the proposed amendment is necessary and was not earlier presented.
 - b. ☐ They raise new issues that would require further consideration and/or search. (See Note).
 - c. ☐ They raise the issue of new matter. (See Note).
 - d. ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.
 - e. ☐ They present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: /

2. ☐ Newly proposed or amended claims _____ would be allowed if submitted in a separately filed amendment cancelling the non-allowable claims.
3. ☒ Upon the filing an appeal, the proposed amendment ☒ will be entered ☐ will not be entered and the status of the claims will be as follows:

Claims allowed: _____
Claims objected to: _____
Claims rejected: 11 AND 12

However;

☐ Applicant's response has overcome the following rejection(s): _____

4. ☐ The affidavit, exhibit or request for reconsideration has been considered but does not overcome the rejection because _____

5. ☒ The affidavit or exhibit will not be considered because applicant has not shown good and sufficient reasons why it was not earlier presented.

☐ The proposed drawing correction ☐ has ☐ has not been approved by the examiner.

☐ Other

CHE S. CHERESKIN
PRIMARY EXAMINER
GROUP 1800

Che S. Chereskin 8/26/94

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Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 11 and 12, drawn to nucleic acid having the sequence of the HIV-1 LTR, classified in Class 536, subclass 24.1.

II. Claims 13 and 14, drawn to a peptide encoded by HIV-1, classified in Class 530, subclass 350+.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Group I and Group II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)). In the instant case HIV proteins may either be synthesized chemically or derived from a natural source, such as the virus.

Also, the nucleic acids of group I have a separate and distinct utility as probes and not necessarily for the expression of the protein of Group II.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and subject matter, as well as their being

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separately and independently searched, restriction for examination purposes as indicated is proper.

In paper No. 5, a response received to a telephone conversation with Kenneth J. Meyers on 30 March 1993, an election was made with traverse to prosecute the invention of Group I, claims 11 and 12. Claims 13 and 14 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

Applicant's election with traverse of Group I, claims 11 and 12, in Paper No. 5 is acknowledged. The traversal is on the ground(s) that "a search of the subject matter of Groups I and II does not appear to impose an undue burden on the Examiner." Applicant is reminded that a search is conducted for relevant art that anticipates or renders obvious claims in distinct subject matter. As such, the search is not co-extensive for Groups I and II. Further, considerations under 35 U.S.C. §§ 101 and 112 are not co-extensive for Groups I and II.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by

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a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

35 U.S.C. § 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 11 and 12 are rejected under 35 U.S.C. § 101 because the invention as claimed lacks patentable utility and as disclosed is inoperative.

Applicant claims nucleic acid having the sequence of the HIV-1 LTR as well as this sequence labeled in various ways. Applicant cites for support the specification page 13, lines 6-15 and page 14, lines 11-19. Page 13, lines 6-15 does set forth what is being claimed, but does not demonstrate a utility for this sequence. On page 14, lines 11-19 the disclosure holds that DNA can be used for "cloned probes". In addition, page 15, lines 18-24, notes of "polypeptides themselves which can be expressed by the different DNAs of the instant inventions, particularly by the ORFs or fragments thereof." Page 17, lines 3-11, specifically states a use for the LTR sequences. By inserting the LTR into a vector, the LTR is "then active as a promoter enabling the efficient transcription and translation in a suitable host of the above defined DNA insert coding for a determined protein placed under its controls."

First, applicant has not demonstrated a utility for the HIV LTR sequences as a probe. How specific is the LTR for detecting HIV? Is there cross-hybridization with other retroviral LTRs, in particular to the HTLV types I and II?

Second, applicant's disclosure states on page 17 that when vectors having the HIV LTR are used to transform human cells, the polymerases of the cell "are capable of recognizing the LTRs of LAV [HIV-1]." However, applicant should be aware of the fact that the HIV-1 LTR is non-functional as a promoter without the presence of the trans-acting factor tat. Consequently, applicant has not demonstrated a utility of the LTR sequences as promoters in the application as filed.

Lastly, applicant notes in the specification, in particular Figure 3, that the nucleic acid claimed lies partially at the 3' end of an open reading frame labeled "ORF-R". Applicant believes that the nucleic acid sequences claimed are translatable into protein having a distinct sequence, such protein thereby having various utilities as stated in the specification. However, applicant has not demonstrated that these nucleic acid sequences comprising the 3' end of "ORF-R" are indeed translated into proteins having a demonstrable utility. Therefore, the nucleic acids as claimed have no demonstrated utility.

Claim 12 is rejected under 35 U.S.C. § 112, first paragraph, as

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the disclosure is enabling only for claims limited to the nucleic acid having the sequence of claim 11. See M.P.E.P. §§ 706.03(n) and 706.03(z).

Applicant has not demonstrated that the nucleic acid claimed has been labeled with any of the labels shown. Labeled nucleic acid as claimed has not been enabled by the specification as filed.

Claim 12 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

How is "an enzyme" used in the labeling of the nucleic acid claimed? Which "enzyme" is being used as the label. Claim 12 contains two typographical errors: "consisiting" and "fluorscent".

The preliminary amendment filed 5 January 1993, paper No. 3, contains contradictory and duplicative information regarding the "Cross-Reference to Related Application" to that filed with the request for filing of a Divisional application under 37 CFR 1.60, paper No. 2, also filed 5 January 1993. Paper No. 3 states that the instant application is a "continuation" of application Serial No. 07/158,652, while paper No. 2 states that the instant application is a "divisional" of application Serial No. 07/158,652. Also, essentially all of this material is duplicative when inserted on page 1, before the first line of the specification. Correction is requested.

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Papers related to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Group 180 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. F. Railey whose telephone number is (703) 308-0281.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

J. Stone
JACQUELINE STONE
PRIMARY EXAMINER
ART UNIT 1834

Johnny F. Railey II
May 25, 1993